UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

006098

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SEP - 4 1986

MEMORANDUM

SUBJECT: EPA File Symbol 55947-UA
CN-11-4962 Herbicide

FROM: Deloris F. Graham DFG 9/12/86
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

E 9/12/86

TO: Robert J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Sandoz Crop Protection Corporation
341 East Ohio Street
Chicago, IL 60611

ACTIVE INGREDIENT:
?% Dicamba . . . . . ?
INERT INGREDIENTS: . . . . . ?

BACKGROUND:

Submitted Acute Oral, Acute Dermal, Primary Dermal Irritatior, Eye Irritation, Dermal Sensitization, and Acute Inhalation Studies. WIL Research Laboratories, Inc. and American Biogenics Corporation conducted these studies. Data under Accession Number 263861. Method of support not indicated.

RECOMMENDATION:

1. FHB/TSS finds these data acceptable to support conditional registration of this product.

2. The appropriate signal word is CAUTION.

LABEL:

Label not submitted with data to be reviewed. Labeling comments will be made upon submission of draft label. Please see enclosed copy for appropriate labeling procedures and format.

REVIEW:

(1) Acute Oral Toxicity Study: WIL Research Lab., Inc., Project Number: WIL-15154; July 24, 1985.

PROCEDURE:

Four groups consisting of five male and five female rats each received one of the following doses orally: 2479, 3000, 3630, and 4392 mg/kg. Observations made frequently on day of dosing, then once daily thereafter for 14 days. Necropsy performed on all animals.

RESULTS:

At 2479 mg/kg, 2/5 M died; at 3000 mg/kg, 2/5 M and 2/5 F died; at 3630 mg/kg, 3/5 M and 2/5 F died; at 4392 mg/kg, 3/5 M and 4/5 F died. Toxic signs reported included ataxia, lethargy, hypertonus, wet tan stains around the mouth, red or brown stains around the nose/mouth. Necropsy report revealed passive congestion of the liver, inflammation of the gastrointestinal mucosa; the inflammation hemorrhagic in the stomach; pulmonary congestion or hyperemia; meningeal hemorrhage or congestion. LD_{50} for males reported to be 3.2998 g/kg with 95% confidence limits between 1.8496 and 5.8872 g/kg. LD_{50} for females reported to be 3.6040 g/kg with 95% confidence limits between 3.0213 and 4.2990 g/kg. LD_{50} for males and females combined reported to be 3.5116 g/kg with 95% confidence limits between 2.8957 and 4.2584 g/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(2) Acute Dermal Toxicity Study: WIL Research Lab., Inc.; Project Number: WIL-15155; May 1, 1985.

PROCEDURE:

Five male and five female rabbits with intact skin sites each received 2000 mg/kg of the test material under occlusive wrap for 24-hour exposure. Observations made for 14 days posttreatment. Necropsy performed on all animals.

RESULTS:

No mortalities reported. Clinical signs noted included dried brown anogenital matting, clear ocular discharge, white nasal discharge. No abnormalities noted on necropsy report. LD_{50} reported to be greater than 2000 mg/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(3) Primary Dermal Irritation Study: WIL Research Lab., Inc.; Project Number: WIL-15156; February 21, 1985.

PROCEDURE:

Six rabbits with intact skin sites each received 0.5 ml of the test material under occlusive wrap for 4-hour exposure period. Observations were made for 72 hours posttreatment.

RESULTS:

At 4.5 hours posttreatment 1/6 animals had slight erythema and edema which had cleared by 24 hours posttreatment. Primary Irritation Index reported to be zero.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

(4) Eye Irritation Study: WIL Research Laboratories, Inc.; Project Number: WIL-15143; February 21, 1985.

PROCEDURE:

Nine rabbits received 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed with 120 ml of tap water for 1 minute, 30 seconds after treatment. Observations made 7 days posttreatment.

RESULTS:

At 24 hours posttreatment, 6/6 rabbits of the unwashed group and 2/3 of the washed group had conjunctive redness (3/6 = 1, 3/6 = 2) (1/3 = 1, 1/3 = 2); 5/6 + 1/3 conjunctive chemosis (1/6 = 1, 4/6 = 2) (1/3 = 2); 1/6 conjunctive discharge (1/6 = 1). Irritation had cleared in all animals in unwashed group by day 7 and in washed animals by day 4.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(5) Skin Sensitization Study: WIL Research Lab., Inc.; Project Number: WIL-15157; July 31, 1985.

PROCEDURE:

Ten male and ten female guinea pigs each received 0.4 ml of the test material undiluted once a week for 3 weeks during induction phase. Two weeks after third induction phase application a 0.4 ml challenge dose was applied to test group as well as to a naive control group (five male and five female guinea pigs). Observations made at 24 and 48 hours after each application.

RESULTS:

At 24 and 48 hours after third induction application of test group animals, 2/10 had very slight (±) irritation. However no irritation was produced at challenge of test group or naive control group. Therefore, it is concluded that this product is not a sensitizing agent.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Nonsensitizing.

(6) Acute Inhalation Toxicity Study: American Biogenics Corporation; Study 420-1981; April 15, 1985.

MRID 00162065; Accession 263861

PROCEDURE:

Three groups consisting of five male and five female rats each were exposed whole-body to one of the following gravimetric concentrations for 4 hours: 4.57, 5.09, or 5.30 g/L. Average mass median diameter reported to be 1.68 micrometers and geometric standard deviation 1.65. Mean chamber temperature reported to be 65.7 °F and relative humidity 40 percent. Observations made for 14 days post-exposure. Necropsy performed on all animals.

RESULTS:

At 4.57 g/L, 1/5 M died; at 5.09 g/L, 1/5 F died; at 5.30 g/L, 1/5 F died. Toxic signs reported included irregular breathing, crusty eye, lethargy, damp fur, alopecia, crusty muzzle, emaciation, squinting, salivation, crusty nose, prostration and poor coat quality. Necropsy report revealed lungs - diffuse red discoloration, right apical lobe; stomach - distended, glandular mucosa; eyes - opacity, bilateral; skin - alopecia, scattered throughout body; small intestines - dark contents; glandular stomach - multifocal black discolorations on mucosa; external surfaces - dark red

exudate around both eyes; mandibular lymph nodes - enlarged, moderate. LC_{50} reported to be greater than 5.30 mg/L maximum attainable concentration.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.